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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/078,903	02/19/2002	Mohamed Bakry	BAKRY-1	4819
26009	7590	07/06/2004	EXAMINER	
ROGER M. RATHBUN 13 MARGARITA COURT HILTON HEAD ISLAND, SC 29926			MCCROSKY, DAVID J	
			ART UNIT	PAPER NUMBER
			3736	

DATE MAILED: 07/06/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/078,903	BAKRY, MOHAMED	
	<b>Examiner</b>	<b>Art Unit</b>	
	David J. McCrosky	3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
  - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 17 May 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-6,9-27 and 29-33 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-6,9,13,16-23,26,27,29,30 and 32 is/are rejected.
- 7) ☒ Claim(s) 10-12,14,15,24,25,31 and 33 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## DETAILED ACTION

### ***Claim Rejections - 35 USC § 102***

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1-4, 6 and 9 are rejected under 35 U.S.C. 102(b) as being anticipated by Rhum et al. The reference discloses an outer tube (11) having a closed distal end and a central canal. Articulating members (17) extend through peripheral openings at the distal end. The articulating members (17) have an operative surface facing the proximal end. See col. 6, ll. 46-50. The articulating members are extended using an inner movable member (19).

It has been held that the functional "whereby" statement does not define any structure and accordingly can not serve to distinguish. *In re Mason*, 114 USPQ 127, 44 CCPA 937 (1957). The preamble has not been given patentable weight because it has been held that a preamble is denied the effect of a limitation where the claim is drawn to a structure and the portion of the claim following the preamble is a self-contained description of the structure not depending for completeness upon the introductory clause. *Kropa v. Robie*, 88 USPQ 478 (CCPA 1951).

Claims 27, 29 and 32 are rejected under 35 U.S.C. 102(b) as being anticipated by Ogirala. The reference discloses a method for a pleural biopsy needle. See col. 1, ll. 6-10. The method includes providing a needle with a closed distal end and an articulating member (9) extending from the distal end. A method of performing the biopsy is disclosed. See col. 4, ll. 12-47. Ogirala further discloses rotating the needle

to move the at least one articulating member. Pin (13), which is attached to the needle, is rotated by rotating the needle itself thereby taking a portion of tissue. See. col. 4, ll. 22-27 and Figs. 2 and 4.

***Claim Rejections - 35 USC § 103***

Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over Rhum et al as applied to claim 1 above. Rhum et al teach the device as recited for claim 1 but do not teach a pointed distal end. It would have been an obvious matter of design choice to modify distal end with a pointed end since Applicant has not disclosed that having a pointed end solves any stated problem or is for any particular purpose and it appears that the device would perform equally well with a pointed end to facilitate movement through tissue.

Claims 13, 16-23 and 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rhum et al in view of Marini. Rhum et al teach an outer tube (11) having a closed distal end and a central canal. Articulating members (17) extend through peripheral openings at the distal end. The articulating members (17) have an operative surface facing the proximal end. See col. 6, ll. 46-50. The articulating members are extended using an inner movable member (19). An outer tube cover (13) is located at the proximal end of the outer tube (11). The handle provides a stop means for the trigger. While disclosing several different embodiments for the articulating members (See Figs. 2-4), Rhum et al do not teach an end tube. Marini discloses a removable end tube (22) to allow usage of various end effectors. See Figs. 2-6. It would have been obvious to one of ordinary skill in the art at the time the invention was

made to modify the apparatus of Rhum et al with the end tube of Marini to allow usage of various end effectors.

Regarding claim 17, it would have been an obvious matter of design choice to modify Rhum et al and Marini by threadedly affixing the outer tube cover since Applicant has not disclosed that having a threaded attachment solves any stated problem or is for any particular purpose and it appears that the apparatus would perform equally well with an attachment of any type.

Regarding claim 18, it would have been an obvious matter of design choice to modify the outer tube cover with wings since Applicant has not disclosed that using wings solves any stated problem or is for any particular purpose and it appears that the apparatus would perform equally well with a means for gripping of any type.

Regarding claim 26, means for aspiration in a biopsy device is well-known in the art.

Claim 30 is rejected under 35 U.S.C. 103(a) as being unpatentable over Ogirala as applied to claim 27 above. Ogirala discloses a method as recited for claim 27. The method accomplishes the same task as claimed but does not teach two articulating members. It would have been obvious to one having ordinary skill in the art at the time the invention was made to add a second articulating member, since it has been held that that mere duplication of parts has no patentable significance unless a new and unexpected result is produced. *In re Harza*, 274 F.2d 669, 124 USPQ 378 (CCPA 1960).

***Allowable Subject Matter***

Claims 10-12, 14, 15, 24, 25, 31 and 33 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

### ***Response to Arguments***

Applicant's arguments filed 17 May 2004 have been fully considered but they are not persuasive.

In response to applicant's argument that the prior art device is not intended for obtaining samples from a pleural cavity, a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the prior art. See *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963).

Here, the intended use language does not define a structural difference between the claimed invention and Rhum et al. Nor does Applicant's allegations of rupturing a lung in the arguments serve to structurally distinguish over Rhum et al.

Examiner maintains the rejection of the method claims. Ogirala discloses rotating the pin (13), attached to the needle, by rotating the needle itself.

### ***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).


A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David J. McCrosky whose telephone number is 703-305-1331. The examiner can normally be reached on Mon-Fri 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mary Beth Jones can be reached on 703-308-3400. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

DJM

  
**MARY BETH JONES**  
ACTING SUPERVISORY PATENT EXAMINER